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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,555	02/15/2002	Rong-Fu Wang	HO-P02373US1	3267

26271 7590 07/13/2005

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EXAMINER	
RAWLINGS, STEPHEN L	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/077,555	WANG, RONG-FU	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

1. The amendment filed September 27, 2004 is acknowledged and has been entered.

2. Claims 1-46 are pending in the application and are currently subject to restriction.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-17 and 19-22, drawn to a composition or a vaccine, said composition or vaccine comprising an effector cell and a cell penetrating peptide associated with an antigen, classified in class 424, subclass 184.1.

Group II. Claim 18, drawn to a composition, said composition comprising an effector cell and a cell penetrating peptide associated with an antibody, classified in class 530, subclass 391.7

Group III. Claims 23-28 and 30-42, drawn to a method for enhancing immunity in an animal to a disease, or of treating the disease in the animal, said method comprising administering to the animal a dendritic cell comprising a cell penetrating peptide associated with an antigen, classified in class 424, subclass 93.1.

Group IV. Claim 29, drawn to a method of immunizing an animal, said method comprising administering to a composition comprising an effector cell and a cell penetrating peptide associated with an antibody, classified in class 424, subclass 178.1.

Group V. Claims 43-46, drawn to a method for preparing a composition for a disease, said method comprising introducing a cell penetrating peptide associated with an antigen into an effector cell, classified, for example, in class 435, subclass 372.

4. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I and II are patentably distinct products, since the inventions of Group I are composition comprising an antibody and the inventions of Group II are composition comprising an antigen. The products of Groups I and II are thus materially and structurally different. Because the products of Groups I and II are distinct, each from the other, the search required to examine claims drawn to either of the products is not the same, nor is it coextensive with the search required to examine claims drawn to the other product. Accordingly, a separate and unique search is required to examine the inventions of Groups I and II; and the need to perform more than one search would be unduly burdensome. Therefore, it is proper to restrict the inventions of Groups I and II. See MPEP § 803.

The inventions of Group III-V are patentably distinct processes, since the inventions of Group III are processes for enhancing immunity in an animal to a disease to treat the disease in the animal, the inventions of Group IV are processes for immunizing an animal, and the inventions of Group V are processes for preparing a composition. Moreover, the inventions of Group III comprise administering to an animal a effector cell comprising a cell penetrating peptide associated with antigen; whereas the inventions of Group IV comprise administering to an animal a composition comprising an effector cell and a cell penetrating peptide associated with an antibody; and the inventions of Group V comprise introducing a cell penetrating peptide associated with an antigen into an effector cell. Accordingly, the processes of Groups III-V are materially different processes, comprising different process steps and having different objectives, and therefore necessarily have different criteria for success and

involve the measurement of different endpoints. Because the processes of Groups III-V are distinct, each from the other, the search required to examine claims drawn to any one of the processes is not the same, nor is it coextensive with the search required to examine claims drawn to the other. Accordingly, a separate and unique search is required to examine the inventions of Groups III-V; and the need to perform more than one search would be unduly burdensome. Therefore, it is proper to restrict the inventions of Groups I and II. See MPEP § 803.

Inventions in Group IV and invention in Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product, such as the process of using the composition to produce effector cells comprising an intracellular antibody conjugated to a cell penetrating peptide.

The inventions of Group I and the inventions of Groups III and V are unrelated because the products of Group I are not specifically used or otherwise involved in the processes of Groups III and V.

The inventions of Group II and the inventions of Groups III and V are unrelated because the products of Group II are not specifically used or otherwise involved in the processes of Groups III and V.

5. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, searching more than

one invention encompassed by the claim would constitute a serious burden; therefore, restriction for examination purposes as indicated is proper.

6. This application contains claims directed to patentably distinct species of the claimed invention, wherein said antigen is selected from the group of tumor antigens listed in the application in, for example, Tables 1-5.

Each species of invention comprising a tumor antigen is distinct from the others comprising a different tumor antigen, as each tumor antigen is structurally distinct from the others. Accordingly, the examination of each species of invention would require a unique search that is not required for examination of any of the other species, because the search of any one tumor antigen will not provide adequate information regarding any other. See MPEP § 809.

Applicant is required under 35 U.S.C. 121 to specifically elect a single species of invention by identifying one tumor antigen, which species of invention will be considered for prosecution on the merits and to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner notes that one novel and nonobvious tumor antigen would render the claims drawn to a species of invention comprising such a tumor antigen allowable over the prior art, but not necessarily over the requirements set forth under 35 U.S.C. §§ 101 and 112.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species, which are written in dependent form, or otherwise, include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order

to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1643

slr
July 7, 2005